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# Pesticide Registration Standard
# Naphthaleneacetic Acid its, Salts
# Ester, and Acetamide

(U.S.) Environmental Protection Agency
Washington, DC

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Pesticides

EPA

# Naphthaleneacetic Acid its, Salts, Ester, and Acetamide

## Pesticide Registration Standard

REPRODUCED BY
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# Naphthaleneacetic Acid
# its Salts, Ester,
# and Acetamide

## Pesticide Registration Standard

| | |
|---|---|
| Michael F. Branagan | Project Manager (SPRD) |
| William Audia | Plant Sciences Specialist (PSB/BFSD) |
| Gary Ballard | Economist (EAB/BFSD) |
| Hudson Boyd | Environmental Chemist (EFB/HED) |
| Dan Dickson | Product Manager (FHB/RD) |
| Nancy Dodd | Residue Chemist (RCB/HED) |
| Linda Garczynski | Writer/Editor (SPRD) |
| Robert Holst | Plant Physiologist (EEB/HED) |
| Thomas Johnston | Wildlife Ecologist (EEB/HED) |
| Ellen Sullivan | Pharmacologist (TB/HED) |

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Environmental Protection Agency

401 M Street, SW

Washington, D.C. 20460

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# CHAPTER I: HOW TO REGISTER UNDER A REGISTRATION STANDARD

A. Organization of the Standard
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## A. Organization of the Standard

This first chapter explains the purpose of a Registration Standard and summarizes the legal principles involved in registering or re-registering under a Standard. The second chapter sets forth the requirements that must be met to obtain or retain registration for products covered by this particular Registration Standard. In the remaining chapters, the Agency reviews the available data by scientific discipline, discusses the Agency's concerns with the identified potential hazards, and logically develops the conditions and requirements that would reduce those hazards to acceptable levels.

## B. Purpose of the Standard

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that "no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive (and having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator [of EPA]." To approve the registration of a pesticide, the Administrator must find, pursuant to Section 3(c)(5) that:

"(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this Act;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

In making these findings, the Agency reviews a wide range of data which registrants are required to submit, and assesses the risks and benefits associated with the use of the proposed pesticide. But the established approach to making these findings has been found to be defective on two counts:

First, EPA and its predecessor agency, the United States Department of Agriculture (USDA), routinely reviewed registration applications on a "product by product" basis, evaluating each product-specific application somewhat independently. In the review of products containing similar components, there was little opportunity for a retrospective review of the full range of pertinent data available in Agency files and in the public literature. Thus the "product by product" approach was often inefficient and sometimes resulted in inconsistent or incomplete regulatory judgments.

Second, over the years, as a result of inevitable and continuing advances in scientific knowledge, methodology, and policy, the data base for many pesticides came to be considered inadequate by current scientific and regulatory standards. Given the long history of pesticide regulation in several agencies, it is even likely that materials may have been lost from the data files. When EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 and 43 FR 37336, August 22, 1978), many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as was being required for new products. Because of this inconsistency, Congress directed EPA to re-register all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements, [See FIFRA Section 3(g)].

Facing the enormous job of re-reviewing and calling-in new data for the approximately 35,000 current registrations, and realizing the inefficiencies of the "product by product" approach, the Agency decided that a new, more effective method of review was needed.

A new review procedure has been developed. Under it, EPA publishes documents called Registration Standards, each of which discusses a particular pesticide active ingredient. Each Registration Standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or reregistration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have, compliance with standards of toxicity, composition, labeling, and packaging, and satisfaction of the data compensation provisions of FIFRA Section 3(c)(1)(D).

The Standard will also serve as a tool for product classification. As part of the registration of a pesticide product, EPA may classify each product for "general use" or "restricted use" [FIFRA Section 3(d)]. A pesticide is classified for "restricted use" when some special regulatory restriction is needed to ensure against unreasonable adverse effects to man or the environment. Many such risks of unreasonable adverse effects can be lessened if expressly-designed label precautions are strictly followed. Thus the special regulatory restriction for a "restricted use" pesticide is usually a requirement that it be applied only by, or under the supervision of, an applicator who has been certified by the State or Federal government as being competent to use pesticide safely, responsibly, and in accordance with label directions. A restricted-use pesticide can have other regulatory restrictions [40 CFR 162.11(c)(5)] instead of, or in addition to, the certified applicator requirement. These other regulatory restrictions may include such actions as seasonal or regional limitations on use, or a requirement for the monitoring of residue levels after use. A pesticide classified for "general use," or not classified at all, is available for use by any individual who is in compliance with State or local regulations. The Registration Standard review compares information about potential adverse effects of specific uses of the pesticide with risk criteria listed in 40 CFR 162.11(c), and thereby determines whether a product needs to be classified for "restricted use." If the Standard does classify a pesticide for "restricted use," this determination is stated in the second chapter.

## C. Requirement to Reregister Under the Standard

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Congress also agreed that reregistration should be accomplished by the use of Registration Standards.

Each registrant of a currently registered product to which this Standard applies, and who wishes to continue to sell or distribute his product in commerce, must apply for reregistration. His application must contain proposed labeling that complies with this Standard.

EPA will issue a notice of intent to cancel the registration of any currently registered product to which this Standard applies if the registrant fails to comply with the procedures for reregistration set forth in the Guidance Package which accompanies this Standard.

## D. "Product Specific" Data and "Generic" Data.

In the course of developing this Standard, EPA has determined the types of data needed for evaluation of the properties and effects of products to which the Standard applies, in the disciplinary areas of Product Chemistry, Environmental Fate, Toxicology, Residue Chemistry, and Ecological Effects. These determinations are based primarily on the data Guidelines proposed in 43 FR 29696, July 10, 1978; 43 FR 37336, August 22, 1978; and 45 FR 72948, November 3, 1980, as applied to the use patterns of the products to which this Standard applies. Where it appeared that data from a normally applicable Guidelines requirement was actually unnecessary to evaluate these products, the Standard indicates that the requirement has been waived. On the other hand, in some cases studies not required by the Guidelines may be needed because of the particular composition or use pattern of products the Standard covers; if so, the Standard explains the Agency's reasoning. Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in effect for some time and are, the Agency believes, relatively familiar to registrants. Data which we have found are needed to evaluate the registrability of some products covered by the Standard may not be needed for the evaluation of other products, depending upon the composition, formulation type, and intended uses of the product in question. The Standard states which data requirements apply to which product categories. (See the third chapter.) The various kinds of data normally required for registration of a pesticide product can be divided into two basic groups:

1. Data that are product specific , i.e. data that relates only to the the properties or effects of a product with a particular composition (or a group of products with closely similar composition); and
2. Generic data that pertain to the properties or effects of a particular ingredient, and thus is relevant to an evaluation of the risks and benefits of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition.

The Agency requires certain "product specific" data for each product to characterize the product's particular composition and physical/chemical properties (Product Chemistry), and to characterize the product's acute toxicity (which is a function of its total composition). The applicant for registration or reregistration of any product, whether it is a manufacturing-use or end-use product, and without regard to its intended use pattern, must submit or cite enough of this kind of data to allow EPA to evaluate the product. For such purposes, "product specific" data on any product other than the applicant's is irrelevant, unless the other product is closely similar in composition to the applicant's. (Where it has been found practicable to group similar products for purposes of evaluating, with a single set of tests, all products in the group, the Standard so indicates.) "Product specific" data on the efficacy of particular end-use products is also required where the exact formulation may affect efficacy and where failure of efficacy could cause public health problems.

All other data needed to evaluate pesticide products concerns the properties or effects of a particular ingredient of products (normally a pesticidally active ingredient, but in some cases a pesticidally inactive, or "inert", ingredient). Some data in this "generic" category are required to evaluate the properties and effects of all products containing that ingredient [e.g., the acute LD-50 of the active ingredient in its technical or purer grade; see proposed 40 CFR 163.81-1(a), 43 FR 37355].

Other "generic" data are required to evaluate all products which both contain a particular ingredient and are intended for certain uses (see, e.g., proposed 40 CFR 163.82-1, 43 FR 37363, which requires subchronic oral testing of the active ingredient with respect to certain use patterns only). Where a particular data requirement is use-pattern dependent, it will apply to each end-use product which is to be labeled for that use pattern (except where such end-use product is formulated from a registered manufacturing-use product permitting such formulations) and to each manufacturing-use product with labeling that allows it to be used to make end-use products with that use pattern. Thus, for example, a subchronic oral dosing study is needed to evaluate the safety of any manufacturing-use product that legally could be used to make an end-use, food-crop pesticide. But if an end-use product's label specified it was for use only in ways that involved no food/feed exposure and no repeated human exposure, the subchronic oral dosing study would not be required to evaluate the product's safety; and if a manufacturing-use product's label states that the product is for use only in making end-use products not involving food/feed use or repeated human exposure, that subchronic oral study would not be relevant to the evaluation of the manufacturing-use product either.

If a registrant of a currently registered manufacturing-use or end-use product wishes to avoid the costs of data compensation [under FIFRA Section 3(c)(1)(D)] or data generation [under Section 3(c)(2)(B)] for "generic" data that is required only with respect to some use patterns, he may elect to delete those use patterns from his labeling at the time he reregisters his product. An applicant for registration of a new product under this Standard may similarly request approval for only certain use patterns.

## E. Data Compensation Requirements under FIFRA 3(c)(1)(D)

Under FIFRA Section 3(c)(1)(D), an applicant for registration, reregistration, or amended registration must offer to pay compensation for certain existing data the Agency has used in developing the Registration Standard. The data for which compensation must be offered is all data which are described by all the following criteria:

1. The data were first submitted to EPA (or to its predecessor agencies, USDA or FDA), on or after January 1, 1970;

2. The data were submitted to EPA (or USDA or FDA) by some other applicant or registant in support of an application for an experimental use permit, an amendment adding a new use to a registration, or for registration, or to support or maintain in effect an existing registration;

3. They are the kind of data which are relevant to the Agency's decision to register or reregister the applicant's product under the Registration Standard, taking into account the applicant's product's composition and intended use pattern(s);

4. The Agency has found the data to be valid and usable in reaching regulatory conclusions; and

5. They are not data for which the applicant has been exempted by FIFRA Section 3(c)(2)(D) from the duty to offer to pay compensation. (This exemption applies to the "generic" data concerning the safety of an active ingredient of the applicant's product, not to "product specific" data. The exemption is available only to applicants whose product is labeled for end-uses for which the active ingredient in question is present in the applicant's product because of his use of another registered product containing that active ingredient which he purchases from another producer.)

An applicant for reregistration of an already registered product under this Standard, or for registration of a new product under this Standard, accordingly must determine which of the data used by EPA in developing the Standard must be the subject of an offer to pay compensation, and must submit with his application the appropriate statements evidencing his compliance with FIFRA Section 3(c)(1)(D).

An applicant would never be required to offer to pay for "product specific" data submitted by another firm. In many, if not in most cases, data which is specific to another firm's product will not suffice to allow EPA to evaluate the applicant's product, that is, will not be useful to the Agency in determining whether the applicant's product is registrable. There may be cases, however, where because of close similarities between the composition of two or more products, another firm's data may suffice to allow EPA to evaluate some or all of the "product specific" aspects of the applicant's product. In such a case, the applicant may choose to cite that data instead of submitting data from tests on his own product, and if he chooses that option, he would have to comply with the offer-to-pay requirements of Section 3(C)(1)(D) for that data.

Each applicant for registration or reregistration of a manufacturing-use product, and each applicant for registration or reregistration of an end-use product, who is not exempted by FIFRA Section 3(c)(2)(D), must comply with the Section 3(c)(1)(D) requirements with respect to each item of "generic" data that relates to his product's intended uses.

A detailed description of the procedures an applicant must follow in applying for reregistration (or new registration) under this Standard is found in the Guidance Package for this Standard.

## F. Obtaining Data to Fill "Data Gaps"; FIFRA 3(c)(2)(B)

Some of the kinds of data EPA needs for its evaluation of the properties and effects of products to which this Standard applies have never been submitted to the Agency (or, if submitted, have been found to have deficiencies rendering them inadequate for making registrability decisions) and have not been located in the published literature search that EPA conducted as part of preparing this Standard. Such instances of missing but required data are referred to in the Standard as "data gaps".

FIFRA Section 3(c)(2)(B), added to FIFRA by the Congress in 1978, authorizes EPA to require registrants to whom a data requirement applies to generate (or otherwise produce) data to fill such "gaps" and submit those data to EPA. EPA must allow a reasonably sufficient period for this to be accomplished. If a registrant fails to take appropriate and timely steps to fill the data gaps identified by a section 3(c)(2)(B) order, his product's registration may be suspended until the data is submitted. A mechanism is provided whereby two or more registrants may agree to share in the costs of producing data for which they are both responsible.

The Standard lists, in the third chapter, the "generic" data gaps and notes the classes of products to which these data gaps pertain. The Standard also points out that to be registrable under the Standard, a product must be supported by certain required "product specific" data. In some cases, the Agency may possess sufficient "product specific" data on one currently registered product, but may lack such data on another. Only those Standards which apply to a very small number of currently registered products will attempt to state definitively the " product specific" data gaps on a "product by product" basis. (Although the Standard will in some cases note which data that EPA does possess would suffice to satisfy certain "product specific" data requirements for a category of products with closely similar composition characteristics.)

As part of the process of reregistering currently registered products, EPA will issue Section 3(c)(2)(B) directives requiring the registrants to take appropriate steps to fill all identified data gaps -- whether the data in question are "product specific" or "generic" -- in accordance with a schedule.

Persons who wish to obtain registrations for new products under this Standard will be required to submit (or cite) sufficient "product specific" data before their applications are approved. Upon registration, they will be required under Section 3(c)(2)(B) to take appropriate steps to submit data needed to fill "generic" data gaps. (We expect they will respond to this requirement by entering into cost-sharing agreements with other registrants who previously have been told they must furnish the data.) The Guidance Package for this Standard details the steps that must be taken by registrants to comply with Section 3(c)(2)(B).

## G. Amendments to the Standard

Applications for registration which propose uses or formulations that are not presently covered by the Standard, or which present product compositions, product chemistry data, hazard data, toxicity levels, or labeling that do not meet the requirements of the Standard, will automatically be considered by the Agency to be requests for amendments to the Standard. In response to such applications, the Agency may request additional data to support the proposed amendment to the Standard, or may deny the application for registration on the grounds that the proposed product would cause unreasonable adverse effects to the environment. In the former case, when additional data have been satisfactorily supplied, and providing that the data do not indicate the potential for unreasonable adverse effects, the Agency will then amend the Standard to cover the new registration.

Each Registration Standard is based upon all data and information available to the Agency's reviewers on a particular date prior to the publication date. This "cut-off" date is stated at the beginning of the second chapter. Any subsequent data submissions and any approved amendments will be incorporated into the Registration Standard by means of addenda, which are available for inspection at EPA in Washington, D.C., or copies of which may be requested from the Agency. When all the present "data gaps" have been filled and the submitted data have been reviewed, the Agency will revise the Registration Standard. Thereafter, when the Agency determines that the internally maintained addenda have significantly altered the conditions for registration under the Standard, the document will be updated and re-issued.

While the Registration Standard discusses only the uses and hazards of products containing the designated active ingredient(s), the Agency is also concerned with the potential hazards of some inert ingredients and impurities.

Independent of the development of any one Standard, the Agency has initiated the evaluation of some inert pesticide ingredients. Where the Agency has identified inert ingredients of concern in a specific product to which the Standard applies, these ingredients will be pointed out in the Guidance Package.

# CHAPTER II: REGULATORY POSITION AND RATIONALE

A. Introduction
B. Description and Relationship of Chemicals
C. Classification Under Minor Use
D. Regulatory Position
E. Regulatory Rationale
F. Criteria for Registration Under the Standard
G. Acceptable Ranges and Limits
H. Required Labeling
I. Tolerance Reassessment

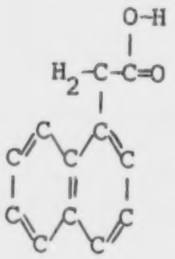
## A. Introduction

This chapter presents the Agency's regulatory position and rationale based on an evaluation of all registered products containing naphthaleneacetic acid, its sodium, potassium and ammonium salts, ester and acetamide as the sole active ingredients. After briefly describing the naphthaleneacetic acid, the parent chemical of this Standard, this chapter presents the regulatory position and rationale, and the criteria for registration of products containing this chemical. These criteria include labeling considerations, and tolerance reassessment. A summary of data requirements is contained in chapter III. Data supporting this regulatory position are discussed in each of the disciplinary chapters, IV through VIII.

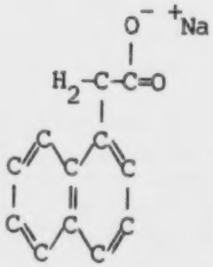
## B. Description of Chemical

Naphthaleneacetic acid (NAA), its sodium and potassium salts, and its ester and acetamide are plant growth regulators which are applied as either a ground or aerial foliar spray to apples, pears, olives, quinces, pineapples and ornamentals.

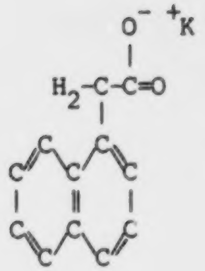
The structural formula for these chemicals are:



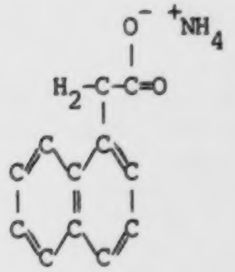
Naphthaleneacetic Acid



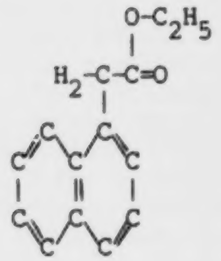
Naphthaleneacetic Acid
Sodium Salt



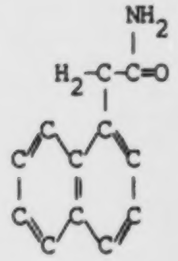
Naphthaleneacetic Acid
Potassium Salt



Naphthaleneacetic Acid
Ammonium Salt



Naphthaleneacetic Acid
Ethyl Ester



Naphthaleneacetic Acid
Acetamide

NAA, its salts, ester and acetamide are combined in this one Standard because they are structurally related and because the Agency has determined that long term toxicity testing should serve for all members of this group of chemicals.

Greenwood Chemical Company, Aceto Chemical Company and Millmaster Onyx Corporation are the principal producers of the manufacturing-use products which are available only as NAA, its sodium salt and its acetamide. Formulated products are available as dusts, soluble concentrates (liquid and solid), wettable powders, granules, pressurized liquids and emulsifiable concetrates.

These chemicals are synthetic plant growth hormones which are used to reduce pre-harvest drop of fruit, to facilitate thinning of fruit trees, induce pineapple flowering, to stimulate root growth on ornamentals, delay leaf drop in holly, prevent fruiting of ornamentals, and control resprouting from pruning wounds on certain decidous trees.

## C. Classification Under Minor Use

End-use products (usually those with less than 25,000 pounds of active ingredient per year) from which exposure is expected to be minimal, based on use rates and patterns, may be classified by the Agency to be minor use chemicals.

The Agency estimates (Not derived from confidential business information estmiates) that the production of NAA and all its salts, ester and acetamide, during the most recent five year period, is between 7,000 to 15,000 pounds of active ingredient in all formulated products per year.

Accordingly, these chemicals are determined to be minor use chemicals. As a result of this classification of minor use, many data requirements, particularly in the areas of Toxicology, Residue Chemistry, Environmental Fate and Ecological Effects have been waived in this Standard. Waiving these requirements is a result of a review of the use patterns and potential exposure to humans and wildlife, which indicates that exposure is likely to be minimal.

## D. Regulatory Position

Based on a review of the available scientific data and other relevant information from the open literature and submitted by registrants as of June, 1981 on naphthaleneacetic acid, its salts, ester and acetamide, the Agency has made the following determinations:

1. Pesticide products containing these chemicals as active ingredients may be registered, subject to the terms and conditions specified in this Standard.

2. None of the risk criteria found in section 162.11(a) of Title 40 U.S. Code of Federal Regulations has been met or exceeded for these active ingredients.

3. No unreasonable adverse effects have been identified for these active ingredients when used in accordance with label directions and limitations.

4. The registrant must develope or agree to develope additional data, specified in chapter III, to maintain the existing registrations or to permit new registrations.

5. The existing tolerances cannot be reassessed at this time because of the limited residue data which are available. The limited residue data which are available indicate that the established tolerances will not be exceeded when use directions are followed.

## E. Regulatory Rationale

Product chemistry, ecological effects, toxicology, residue chemistry and environmental fate data available to support the registration of naphthaleneacetic acid, its salts, ester and acetamide are extremely limited. Therefore, no quantitative hazard or risk estimate could be performed for these chemicals.

Exposure to these chemicals may occur through consumption of residues retained in or on fruit and during application and mixing/loading of the formulated product. Tolerances have been established for NAA on apples, pears and quinces at 1 ppm, on olives at 0.1 ppm and on pineapples (as the sodium salt) at 0.05 ppm. Tolerances have also been established for the ethyl ester of NAA at 1 ppm on apples and pears and 0.1 ppm on olives. Tolerance of 0.1 ppm have been established for naphthaleneacetamide on apples and pears. These tolerances are for NAA. Metabolites are not included in the tolerance expression.

Because residue data are insufficient to properly reassess these tolerances, the Agency has decided to request residue data in plants. While existing residue data are meager, the Agency currently has no reason to suspect that exposure to NAA, via residues on food, will cause adverse effects. After submission of the required residue data, the Agency will reexamine the current tolerances.

Spray drift during application is not expected to be a major vehicle of exposure because of the high use-dilutions of these chemicals. Mixing/loading of these chemicals, because of contact with the concentrated product, is anticipated to result in significant respiratory, dermal and ocular exposure, and is thus considered to be the major route of exposure. The use of goggles and gloves will significantly reduce exposure during mixing/loading of end-use products. Although dermal exposure to end-use products is high during application to ornamentals, the methods of application and high use-dilutions preclude significant exposure.

While data to assess the environmental fate of NAA do not meet the current requirements, the Agency has determined that further environmental fate testing is not required at this time because of the low application rates and minor use status of these chemicals.

The Agency has not reviewed efficacy data for these chemicals because their use does not affect the public health.

Although some data gaps remain, the Agency has concluded that it should continue the registration for this chemical for the following reasons:

1. No adverse effects data of regulatory concern have been uncovered in the review of the available studies which have been received, either in studies sufficient to meet data requirements or in those which fail to meet data requirements but which provide some basis for a qualitative judgement.

2. No significant effects have been reported in the limited accident data for these chemicals.

3. In accordance with FIFRA, the Agency's policy is not to routinely cancel the registration of products merely because we lack data, or to withhold registration merely for the lack of data. (See sections 3(c)(2)(B) and 3(c)(7) of FIFRA.) Rather, publication of the Standard provides a mechanism for identifying data needs, and registration under the Standard allows for upgrading of labels during the period in which the required data are being generated. When these data are received, they will be reviewed by the Agency. The Agency will then determine whether these data will affect the registration of this chemical.

## F. Criteria for Registration Under the Standard

To be subject to this Standard, products must meet the following conditions:

- contain naphthaleneacetic acid, its salts, ester or acetamide; as single active ingredients and
- bear required labeling; and
- conform to the acute toxicity limits, product composition and use pattern requirements stated in section G below.

The applicant for registration or reregistration of products subject to this Standard must comply with all terms and conditions described in this Standard including a commitment to fill data gaps on a time schedule specified by the Agency and, when applicable, offering to pay compensation to the extent required by 3(c)(1)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, 7 U.S.C. 136(c)(1)(D). As discussed in Chapter I, applicants for registration under this Standard must contact the Registration Division for specific instructions, including updated information contained in the guidance package on data requirements and companies whose data must be cited and to whom compensation must be offered.

## G. Acceptable Ranges and Limits

### 1. Manufacturing-Use Products

#### a. Product Composition Standard

Currently the Agency has no information on acceptable ranges and limits for the product composition of manufacturing-use products containing these chemicals. To be covered under this Standard, manufacturing-use products containing these chemicals must propose acceptable ranges and limits for both active and inert ingredients.

#### b. Acute Toxicity Limits

The Agency will consider registration of manufacturing-use products containing these chemicals regardless of the toxicity category, provided that they bear appropriate precautionary labeling.

#### c. Use Patterns and Application Methods

To be registered under this standard, manufacturing-use products containing these chemicals must be labeled to allow for formulation only into end-use products which are intended for use as:

1) synthetic plant growth hormones for use on apples, pears, olives for thinning of fruit, and/or apples and pears to prevent preharvest drop of fruit, and/or pinapples to induce flowering.

2) synthetic plant growth hormones for use on ornamentals to stimulate root growth, to delay leaf drop in holly, to prevent fruiting of ornamental olive, catalpa, elm, horsechestnut and maple trees, and to control resprouting from pruning wounds on certain deciduous trees.

2. End-Use Products

a. Product Composition Standard

Currently the Agency has no information on acceptable ranges and limits for the product composition of end-use products containing NAA, its salts ester and acetamide. To be covered under this Standard, end-use products containing these chemicals must propose acceptable ranges and limits for both active and inert ingredients.

b. Acute Toxicity Limits

The Agency will consider registration of end-use products containing these chemicals under a general-use classification, regardless of their toxicity category, provided that they bear appropriate precautionary labeling.

c. Use Patterns and Application Methods

Currently, end-use products containing these chemicals are labeled as plant growth regulators for one or more of the uses specified in table 1.

TABLE 1

Use Sites for NAA, its Salts, Ester and Acetamide

| PRODUCT TYPE | USE SITE | ACTIVE INGREDIENT |
|---|---|---|
| DUSTS | Apples | NAA only |
| | Ornamentals | Acetamide only |
| WETTABLE POWDERS | Apples & Pears | NAA, Sodium Salt, Acetamide |
| | Ornamentals | Sodium Salt only |
| EMULSIFIABLE CONCENTRATES | Apples & Pears | NAA only |
| SOLUBLE CONCENTRATES/ LIQUIDS | Apples | NAA, Ammonium & Potassium Salts, Acetamide |
| | Pears | NAA, Ammonium & Potassium Salts |
| | Olives | Potassium Salt only |
| | Ornamentals | NAA, Potassium & Ammonium Salts |
| SOLUBLE CONCENTRATES/ SOLIDS | Apples & Pears | Sodium Salt only |
| CRYSTALLINE | Pineapples | Sodium Salt only |
| READY-TO-USE PRESSURIZED LIQUIDS | Ornamentals | Ester only |

Under this Standard, end-use products containing any of the chemicals covered in this Standard may be registered for any of the sites listed in table 1, provided that those uses are appropriately covered by existing tolerances.

## H. Required Labeling

All manufacturing-use and end-use products containing these chemicals must bear labeling as specified in 40 CFR 162.10. The guidance package for this Standard contains specific information regarding label requirements. In addition, the following specific labeling is required:

1. Manufacturing-Use Products

All manufacturing-use products containing these chemicals must bear one or both of the following statements on the label:

"For reformulation into products intended as growth regulators of ornamentals."

"For reformulation into products intended as growth regulators for apples, quinces, pears, pineapples, and/or olives."

These statements are necessary to identify the applicability of those data requirements which are used to support manufacturing-use products intended for use on food crops.

2. End-Use Products

Except for those end-use products containing methanol or the ethyl ester, there are no unique precautionary statements which must appear on labeling of all presently registered end-use products containing the chemicals covered in this Standard.

a. Methanol

All end-use products containing methanol must bear the following statement:

"Contains methanol"

All end-use products which contain greater than 4 percent methanol must bear the following additional statement:

"DANGER (skull & crossbones) POISON"

"Methanol may cause blindness. Harmfull or fatal if
swallowed. Vapor harmful. Avoid breathing spray,
mist or vapors. Avoid contact with skin."

b. Ethyl Ester

Based on data available on currently registered products, soluble concentrate end-use products which presently contain 15.1% of the ethyl ester of NAA must bear labeling indicating that the product is corrosive to the eyes and irritating to the skin. Products presently containing this chemical must bear label recommendations for the use of goggles (or face shield) and gloves.

Refer to the guidance package for an updated list of all precautionary statements which must appear on these types of products. The Agency may, after review of the data to be submitted under this Standard, impose additional label requirements.

## I. Tolerance Reassessment

Tolerances have been established for NAA on apples, pears, and quinces at 1 ppm; on olives at 0.1 ppm; and in or on pineapples at 0.05 ppm (as the sodium salt). Tolerances have also been established for the ethyl ester on apples and pears at 1 ppm and on olives at 0.1 ppm. Tolerances of 0.1 ppm for the acetamide of NAA have been established on apples and pears. No CODEX tolerances exist for these chemicals.

Based on established tolerances, the theoretical human exposure to residues is calculated to be 0.0425 mg/dy/1.5 kg of diet. This figure is based on the average adult eating patterns and on the assumption that the foods contain residues which meet the established tolerance levels.

Currently a tolerance of 1 ppm exists for NAA and its ethyl ester. The limited amount of residue data currently available in addition to theoretical estimates of residues, indicate that residues of these chemicals are significantly lower than the present 1 ppm tolerance. The Agency has determined that some additional residue data are required to confirm the previously measured residues. If the requested data detect residues which are higher than those previously measured additional toxicological data may be required to support the present uses. Any future requests for new uses and/or tolerances may result in the requirement for additional toxicological, environmental fate, ecological effects and residue chemistry data.

## CHAPTER III: SUMMARY OF DATA REQUIREMENTS AND DATA GAPS

A. Introduction
B. Group A Charts: Generic Data Requirements
C. Group B Charts: Manufacturing-Use Data Requirements
D. Group C Charts: End-Use Product-Specific Data Requirements

### A. Introduction

Applicants for registration of end-use naphthaleneacetic acid, its salts, ester and acetamide products must cite or submit the following information on the physical/chemical properties, composition, fate, residue chemistry, ecological effects and toxicity of the proposed product. Data in this Standard that satisfy registration requirements may be cited, if the applicant establishes that the proposed product is substantially similar to another product for which the Agency has received acceptable acute toxicity tests. Data may be cited provided compensation has been offered to the submitters of these studies. The Agency will consider both active and inert ingredients in the determination of substantially similar products. (See Chapter I for discussion of substantially similar products).

The section of the Proposed Guidelines which describes the type of data and when it is required is listed before each requirement listed [43 FR, 29696 of July 10, 1978; and 43 FR, 37336 of August 22, 1978]. Justification for the required tests is provided in the Guidelines. Areas where this Standard differs from the Guidelines are discussed in the Regulatory Rationale section of Chapter II. Applicants for the reregistration of manufacturing-use or end-use products containing naphthaleneacetic acid, its salts, ester and acetamide must submit all information identified as data gaps for manufacturing-use and end-use products, respectively (see charts). The footnotes to the charts offer an explanation of additional data requirements or data waivers outside of the guidelines. The data requirements specified are the minimum that will be required. Areas where additional data may be required as the result of tiered testing are indicated.

## DATA REQUIREMENTS CHART A

## Naphthaleneacetic Acid, its Salts, Ester & Acetamide

### Generic Data Requirements: TOXICOLOGY

| Guidelines Citation | Name of Test | Are Data Required? | Composition | Does EPA have data to partially or totally satisfy this requirement? | Bibliographic Citation | Must additional data be submitted under FIFRA 3(c)(2)(B)? If so, due when? |
|---|---|---|---|---|---|---|
| **A. Naphthaleneacetic Acid** | | | | | | |
| 163.81-1 | Acute Oral Toxicity | yes | Technical Grade of Active Ingredient | no | - | yes/6 months |
| 163.81-2 | Acute Dermal Toxicity | yes | Tech. Grade of A.I. | no | - | yes/6 months |
| 163.81-3 | Acute Inhalation Toxicity | yes | Tech. Grade of A.I. | no | - | yes/6 months |
| 163.81-4 | Primary Eye Irritation | yes | Tech. Grade of A.I. | no | - | yes/6 months |
| 163.81-5 | Primary Skin Irritation | yes | Tech. Grade of A.I. | no | - | yes/6 months |
| 163.81-6 | Dermal Sensitization | yes | Tech. Grade of A.I. | no | - | yes/6 months |
| 163.82-1 | Subchronic Oral Toxicity | yes | Tech. Grade of A.I. | yes | GS0023002,GS0023001<br>005008106,GS0023031 | no |
| 163.83-1 | Chronic Feeding | yes | Tech. Grade of A.I. | no | - | no [1] |
| 163.83-2 | Oncogenicity | yes | Tech. Grade of A.I. | no | - | no [1] |
| 163.83-3 | Teratogenicity | yes | Tech. Grade of A.I. | partial | GS0023044 | yes/18 Months |
| 163.83-4 | Reproduction | yes | Tech. Grade of A.I. | no | - | no [1] |
| 163.84-2 through -4 | Mutagenicity | yes | Tech. Grade of A.I. | yes | 005008826,GS0023037,<br>GS0023038,GS0023039,<br>GS0023040,GS0023041,<br>GS0023042,GS0023043, | no |
| 163.85-1 | Metabolism (Identification of Metabolites) | yes | Radiolabeled Analytically Pure Grade of Active Ingredient | yes | 000004942,005008052 | no |
| **B. Naphthaleneacetic Acid, Ammonium Salt** | | | | | | |
| 163.81 | Acute Toxicity Testing | [2] | | | | |
| 163.81-4 | Primary Eye Irritation | yes | Tech. Grade of A.I. | no | | yes/6 months |

In addition to the above data that will be provided for the fulfilmentof the requirements for the ammonium salt, the data on NAA will be considered for manufacturing use products containing the ammonium salt.

C. Naphthaleneacetic Acid, Sodium & Potassium Salts

The data for NAA will be considered for manufacturing use products containing the sodium and potassium salts.

D. Naphthaleneacetic Acid, Ethyl Ester

| | | | | | | |
|---|---|---|---|---|---|---|
| 163.81-1 | Acute Oral Toxicity | yes | Technical Grade of Active Ingredient | yes | GS0023048 | no |
| 163.81-2 | Acute Dermal Toxicity | yes | Tech. Grade of A.I. | yes | GS0023047 | no |
| 163.81-3 | Acute Inhalation Toxicity | yes | Tech. Grade of A.I. | yes | GS0023046 | no |
| 163.81-4 | Primary Eye Irritation | yes | Tech. Grade of A.I. | yes | GS0023045 | no |

In addition to the above data that will be provided for the fulfilmentof the requirements for the ethyl ester, the data on NAA will be considered for manufacturing use products containing the ethyl ester.

E. Naphthaleneacetamide

The data for NAA will be considered for manufacturing use products containing the acetamide of NAA.

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These data requirements are current as of June, 1981. Refer to the guidance package for updated requirements.

1.Studies currently available, although inadequate by current standards, do not indicate major concerns in these areas. No further testing is required at this time.

2.The requirement for this test will be determined once acute toxicity data are available for NAA.

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## DATA REQUIREMENTS CHART A

Naphthaleneacetic Acid, its Salts, Ester & Acetamide

Generic Data Requirements:RESIDUE CHEMISTRY

| Guidelines Citation | Name of Test | Are Data Required? | Composition | Does EPA have data to partially or totally satisfy this requirement? | Bibliographic Citation | Must additional data be submitted under FIFRA 3(c)(2)(B)? If so, due when? |
|---|---|---|---|---|---|---|
| - | Metabolism in Plants | yes | Representative Formulations | yes | 000004943,005009196 | no 2 / |
| - | Metabolism in Animals | yes | Representative Formulations | yes | 005007966,005008070,<br>000004942,005008052,<br>005008057 | no 2 / |
| - | Analytical Methods | yes | Representative Formulations | yes | 000004943,000004916,<br>005007967,005020083,<br>000004946,005002768,<br>005008121,005008068,<br>GS0023012,GS0023019,<br>GS0023036 | no |
| - | Residue Data:<br>Crops- Apples<br>Pears<br>Pineapples<br>Olives | yes | Representative Formulations | partial | 000004943,GS0023012<br>GS0023019,GS0023036 | yes/18 months 1 / 2 / |
| - | Dissociation Data | yes | Each A. I. | no | - | yes/12 months 2 / 3 / |

These data requirements are current as of June, 1981. Refer to the guidance package for updated requirements.

1.Degradation data indicate that residues in plants of ester, salts and acetamide of NAA degrade rapidly to residues of NAA and that these residues are of the same order of magnitude as those for NAA. - Additional data are required to confirm the degradation of these chemicals.

2.This data is for the technical chemicals intended for use on food crops only.

3.Data on the dissociation or hydrolyzation of these chemicals must be submitted.

July, 1981

## DATA REQUIREMENTS CHART A

Naphthaleneacetic Acid, its Salts, Ester & Acetamide

Generic Data Requirements: ECOLOGICAL EFFECTS

| Guidelines Citation | Name of Test | Are Data Required? | Composition | Does EPA have data to partially or totally satisfy this requirement? | Bibliographic Citation | Must additional data be submitted under FIFRA 3(c)(2)(B)? If so, due when? |
|---|---|---|---|---|---|---|
| 163.71-1 | Avian Single-Dose Oral $LD_{50}$ | yes | Tech. Grade of NAA | yes | GS0023023,GS0023024 | no |
| 163.71-2 | Avian Dietary $LC_{50}$ | yes | Tech. Grade of NAA | yes | GS0023025,GS0023026 | no |
| 163.72-1 | Fish Acute $LC_{50}$ | yes | Tech. Grade of NAA | partial | GS0023022,GS0023051 | yes/6 months |
| 163.72-2 | Acute Toxicity to Aquatic Invertebrates | yes | Tech. Grade of NAA | partial | GS0023050 | yes/6 months |
| 163.122-1 | Seed Germination | yes | Tech. Grade of NAA | yes | 005010399,005012526 | no |
| 163.122-1 | Vegatative Vigor | yes | Tech. Grade of NAA | yes | 005007254,005007255 | no |
| 163.122-1 | Effects on Terrestrial Macrophytes | yes | Tech. Grade of NAA | no | - | yes/6 months |
| 163.122-2 | Effects on Aquatic Macrophytes | yes | Tech. Grade of NAA | no | - | yes/6 months |
| 163.122-2 | Effects on Algae | yes | Tech. Grade of NAA | no | - | yes/6 months |

These data requirements are current as of June, 1981. Refer to the guidance package for updated requirements.

July, 1981

## DATA REQUIREMENTS CHART B

### Naphthaleneacetic Acid, its Salts, Ester & Acetamide

### Manufacturing-Use Data Requirements: PRODUCT CHEMISTRY

| Guidelines Citation | Name of Test | Are Data Required? | Composition | Does EPA have data to partially or totally satisfy this requirement? | Bibliographic Citation | Must additional data be submitted under FIFRA 3(c)(2)(B)? If so, due when? |
|---|---|---|---|---|---|---|
| 163.61-3 | Product Identity & Disclosure of Ingredients | yes | Each Product | no | - | yes/6 months 1 / 4 / |
| 163.61-4 | Description of Manufacturing Process | yes | Each Product | partial | - | yes/6 months 2 / 4 / |
| 163.61-5 | Discussion on Formulation of Unintentional Ingredients | yes | Each Product | no | - | yes/6 months 4 / |
| 163.61-6 | Declaration & Certification of Ingredients Limits | yes | Each Product | no | - | yes/6 months 3 / 4 / |
| 163.61-7 | Product Analytical Methods & Data | yes | Each Product | no | - | yes/6 months |
| 163.64 | Physical & Chemical Properties | yes | Tech. Grade of A.I. & Each Product | no | - | yes/ 4 / |

These data requirements are current as of June, 1981. Refer to the guidance package for updated requirements.

1. All impurities and inerts in the technical chemicals produced by or for Greenwood Chemical Company, Millmaster Onyx Corporation and Aceto Chemical Company must be identified. Formulations of all other technical products and chemicals covered by this Standard must be identified.

2. Complete information must be supplied by each manufacturer on the present manufacturing process, including data listed in 43 FR 29709.

3. The upper and lower limits of each active and inert ingredient in manufacturing-use and end-use products must be declared and certified. The upper limit for each impurity, reaction product and degradation product must be provided. If not already cleared, all inert ingredients contained in products with food uses must be cleared by the registrant with the Food and Drug Administration.

4. These requirements must be fulfilled by each applicant. Data from other applicants may not be cited. Therefore, even if the requirement has been partially or completely fulfilled for some products, no references are given. Except for 163.61-7, these requirements must be fulfilled at the above dates.

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## DATA REQUIREMENTS CHART C

### Naphthaleneacetic Acid, its Salts, Ester & Acetamide

### End-Use Product-Specific Data Requirements: PRODUCT CHEMISTRY

| Guidelines Citation | Name of Test | Are Data Required? | Composition | Does EPA have data to partially or totally satisfy this requirement? | Bibliographic Citation | Must additional data be submitted under FIFRA 3(c)(2)(B)? If so, due when? |
|---|---|---|---|---|---|---|
| 163.61-3 | Product Identity & Disclosure of Ingredients | yes | Each Product | no | - | yes/6 months 3 / |
| 163.61-4 | Description of Manufacturing Process | yes | Each Product | no | - | yes/6 months 1 / 3 / |
| 163.61-5 | Discussion on Formulation of Unintentional Ingredients | yes | Each Product | no | - | yes/6 months 3 / |
| 163.61-6 | Declaration & Certification of Ingredients Limits | yes | Each Product | no | - | yes/6 months 2 / 3 / |
| 163.61-7 | Product Analytical Methods & Data | yes | Each Product | yes | - | no 4 / |
| 163.64 | Physical & Chemical Properties | yes | Each Product | no | - | yes/6 months 3 / |

These data requirements are current as of June, 1981. Refer to the guidance package for updated requirements.

1.Complete information must be supplied by each manufacturer on the present manufacturing process, including data listed in 43 FR 29709.

2.The upper and lower limits of each active and inert ingredient in manufacturing-use and end-use products must be declared and certified. The upper limit for each impurity, reaction product and degradation product must be provided. If not already cleared, all inert ingredients contained in products with food uses must be cleared by the registrant with the Food and Drug Administration.

3.These requirements must be fulfilled by each applicant. Data from other applicants may not be cited. Therefore, even if the requirement has been partially or completely fulfilled for some products, no references are given. Except for 163.61-7, these requirements must be fulfilled at the above dates.

4.This data will not be required because of the minor use status of these chemicals.

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## DATA REQUIREMENTS CHART C

### Naphthaleneacetic Acid, its Salts, Ester & Acetamide

### End-Use Product-Specific Data Requirements: TOXICOLOGY

| Guidelines Citation | Name of Test | Are Data Required? | Composition | Does EPA have data to partially or totally satisfy this requirement? | Bibliographic Citation | Must additional data be submitted under FIFRA 3(c)(2)(B)? If so, due when? |
|---|---|---|---|---|---|---|
| SOLUBLE CONCENTRATES | | | | | | |
| A. Naphthaleneacetic Acid | | | | | | |
| 163.81-4 | Primary Eye Irritation | yes | Each Formulation or Substantially Similar Formulations Containing >50% Diacetone or Petroleum Oil | no | - | yes/6 months |
| B. Potassium Salt of Naphthaleneacetic Acid | | | | | | |
| 163.81-4 | Primary Eye Irritation | yes | Each Formulation or Substantially Similar Formulations Containing >25% Isopropanol | no | - | yes/6 months |
| C. Naphthaleneacetic Acid, Ethyl Ester | | | | | | |
| 163.81-1 | Acute Oral Toxicity | yes | Each Formulation or Substantially Similar Formulations | yes | GS0023035 | no |
| 163.81-2 | Acute Dermal Toxicity | yes | Each Formulation or Substantially Similar Formulations | yes | GS0023032 | no |
| 163.81-3 | Acute Inhalation Toxicity | yes | Each Formulation or Substantially Similar Formulations | yes | GS0023034 | no |
| 163.81-4 | Primary Eye Irritation | yes | Each Formulation or Substantially Similar Formulations | yes | GS0023033 | no |
| D. Naphthaleneacetamide | | | | | | |
| 163.81-4 | Primary Eye Irritation | yes | Each Formulation or Substantially Similar Formulations Containing >50% Isopropanol and Fertilizer | no | - | yes/6 months |

These data requirements are current as of June, 1981. Refer to the guidance package for updated requirements.

July, 1981

# CHAPTER IV: PRODUCT CHEMISTRY

A. Product Chemistry - Manufacturing-Use Products
B. Product Chemistry - End-Use Products
C. Physical and Chemical Properties
D. Analytical Methods
E. Summary of Data Gaps

FIFRA 3(c)(2)(A) requires the Agency to establish guidelines for registering pesticides in the United States. We require registrants to provided quantitative data on all added ingredients, active and inert, which are equal to or greater than 0.1% of the product by weight.

To establish the composition of products proposed for registration, the Agency requires data and information not only on the manufacturing and formulation processes, but also a discussion on the formation of manufacturing impurities and other ingredients, intentional and unintentional. further, to assure that the composition of the product as marketed will not vary from the composition evaluated at the time of registration, applicants are required to submit a statement certifying upper and lower limits for the added ingredients, and upper limits only for some unintentional ingredients. Subject D suggests specific precision limits for ingredients based on the percentage of ingredient and the standard deviation of the analytical method.

In addition to the data on product composition, the Agency also requires data to establish the physical and chemical properties of both the pesticide active ingredient and its formulations. For example, data are needed concerning the identity and physical states of the active ingredient (e.g., melting point and boiling point data, ambient vapor pressure and solubility). Data are also required on the properties of the formulated product to establish labeling cautions (e.g., flammability, corrosivity or storage stability). The Agency uses these data to characterize each pesticide and to determine its environmental and health hazards.

## A. Product Chemistry Manufacturing-Use Product

The technical grade of naphthaleneacetamide contains 98 percent of the acetamide. The other technical grades contain 98 or 98.5 percent of naphthaleneacetic acid or its sodium salt. The lack of identification of impurities constitutes a data gap which must be filled. The physical/chemical properties for technical 1-naphthaleneacetic acid and related chemicals covered by this Standard are not available. In addition, the inert ingredients in many manufacturing-use products containing these chemicals are not available and constitute data gaps.

Several related chemicals (the ammonium, potassium and sodium salts, the ethyl ester of naphthaleneacetic acid, and naphthaleneacetamide) are considered a part of this Standard. The lack of product chemistry data on these chemicals constitutes a data gap. Product chemistry data must be submitted on each individual chemical.

## B. Product Chemistry - End-Use Products

There is little product chemistry data on many end-use products. The lack of product chemistry data for these pesticides constitutes a data gap. Product chemistry data must be submitted for all end-use products containing these chemicals. The ingredients of all formulations must be identified to 0.1% in accordance with the proposed guidelines. Those ingredients which have been added intentionally to a food-use formulation must also be cleared under 40 CFR 180.1001. The identification of the inert ingredients in many end-use products containing these chemicals are either not available or these ingredients have not been cleared as inert ingredients in pesticides used on food crops. Theseconstitute data gaps.

## C. Physical and Chemical Properties

The physical and chemical properties can serve as a means of chemical identification or as a confirmation of the reliability of other composition data. The physical and chemical properties of technical, manufacturing-use and formulated products containing NAA, its salts, ester and acetamide are generally not available and, hence, constitute data gaps.

## D. Analytical Methods

In order to ensure that products contain only those percentages of active ingredients which they properly claim to contain, it is necessary to have analytical methods to determine the concentration of active ingredients in each formulation. In addition, the commercial production of pesticide chemicals, reactions between pesticide ingredients, reactions with packaging materials, as well as degradation during the long period over which some products may be stored before use, can result in the formation of chemical impurities. Because of the potential toxicity of these impurities, the Agency may require submittal of analytical methods for their assessment, both to improve the reliability of the Agency's hazard assessment and to ensure that marketed products conform to the standards of purity agreed upon by the pesticide producer.

Analytical methods for the determination of the percentage of NAA in Fruit Fix Superconcentrate 800 (Crosby et al., MRID 000004943) and the percentage of the ethyl ester of NAA in Amchem Sprout Inhibitor A112 (Amchem Products, MRID GS-0023-012; Amchem Products, MRID GS-0023-019; Amchem Products, MRID GS-0023-036) are inadequate by present scientific standards. The Agency has determined that validation data (e.g. background values, recoveries, and method of sensitivity for the active ingredient) for all formulations and analytical methods for the identification and quantification of the active ingredients in all other formulations, normally required for these chemicals, will not be required because of the minor use status of these chemicals.

## E. Summary of Data Gaps

A summary of the data gaps for product chemistry are listed in Chapter III.

# CHAPTER V: ENVIRONMENTAL FATE

A. Use Profile
B. Environmental Fate Profile - Manufacturing-Use Products
C. Exposure Profile - End-Use Products
D. Summary of Data Gaps

## A. Use Profile

Naphthaleneacetic acid, its salts, ester and acetamide are plant growth regulators registered to (1) prevent pre-harvest drop of apples, pears, quinces, olives, (2) thin fruit trees, (3) induce flower induction in pineapples, (4) stimulate root growth on ornamentals and (5) delay leaf drop on ornamentals. 7,000 to 15,000 pounds of active ingredient are produced per year with the major portion used on apples and pears. Pineapples and ornamentals are a small portion of the sites for these chemicals.

The abcission or lossening of uninjured fruits on a tree is a natural part of the maturation process in fruit. The formation of a callous abcission (separation) layer at the juncture of the fruit stem and the spur allows the weakly held fruit to fall at maturity. NAA reduces release of fruit from trees by slowing the formation of the abscission layer.

Because of its low solubility in water (0.042 g/100 ml), naphthaleneacetic acid is usually sold in the form of a salt, ester or acetamide. Even though these forms of NAA increase its solubility, NAA is reformulated with various inert ingredients (alcohol, acetone, etc.) to promote even dispersal in use dilutions of end-use products. These chemicals are formulated into dusts, wettable powders, emulsifiable concentrates, soluble concentrates/liquid, soluble concentrates/solids, granulars, pressurized liquids and ready-to-use liquids. The percentage of active ingredient in these formulations varies from 0.002 to 98 percent.

These chemicals may be applied by either ground and aerial application equipment at a concentration of approximately 10 ppm, but it may be necessary to vary the concentration of these chemicals to obtain good drop control of certain varieties of fruit. Application is made approximately 10 days prior to picking or at the first sign of sound, fully seeded fruit dropping from the tree. Longer periods of drop control may be obtained in apples by spraying 14 to 20 days prior to picking with a repeat application seven to ten days later.

Coverage of the entire fruit tree is essential because these chemicals are absorbed through the foliage and translocated only short distances within the tree stems to the fruit. Application of these chemicals is usually accomplished by ground rigs from air-blast sprayers. Approximately 1500 to 2000 gallons of spray solution is applied on three to five acres per hour. A maximum of 70 acres of mature fruit bearing trees can be covered in a ten hour day. The timing and rate of application is very critical because these chemicals require approximately three days to become effective and their effectiveness lasts from

10 to 14 days. Premature application will not prevent pre-harvest drop because their effect will dissipate before drop begins. Late application will deliver little or no benefit. To maintain effectiveness, application should be made at temperatures above 70°F and when rain will not occur for several hours.

The thinning of fruit from trees is an essential part of orchard management. The process of thinning involves the removal, by hand or chemical spraying, of immature fruit. Thinning results in larger, more uniform fruit size, reduces the size of fluctuations between harvests for biennial bearing trees, reduces limb breakage, and maintains tree vigor.

Historically, thinning was performed by removing, by hand, of immature fruit after a natural drop. Depending on the anticipated crop size, growers attempted to strive for a uniform number of fruit per tree, or per cluster on a tree.

Thinning with chemical agents, such as NAA, provides a means to partially or completely overcome the necessity of hand thinning and has now become a standard commercial practice in many fruit growing areas of the U.S.

Chemical thinning agents are usually sprayed while the fruit is still susceptable to the thinning effect, but after the leaves have reached a point in their development where injury to foliage would be least likely to occur. Because the results of thinning are highly variable, directions for use will depend on the weather, amount of bloom, pollination, rate of application, time of application and region of the country where the chemical is used.

The effectiveness of chemical thinning also depends upon the rate of absorption by the leaves of the fruit tree. Absorption of thinning agents will vary between fruits and between varieties of a fruit as well as whether a wetting agent is used during application. Concentrations of these chemicals may be lowered by 50% the recommended rates when a wetting agent is used in the spray solutions. Finally, insufficient thinning one year does not necessarily warrent an increase in the concentration the next year.

Thinning may be performed with either high or low volume equipment. The main objective of effective spraying is calculation of proper dosage rates and application of these chemicals to each tree so that each tree is thouroughly covered. Failure to perform proper dosing and uniform coverage may result in low thinning activity. Spray concentrations of up to 20 ppm are used for thinning apples, up to 50 ppm for pears, and up to 150 ppm for thinning olives.

NAA is also used to induce flowering of pineapples at a rate of 25 grams A.I. per acre applied as a spray solution. It is applied when most of the crop is still in the vegetative stage. No more than two applications are made to the crop.

## B. Environmental Fate Profile

Limited data are available to assess the environmental fate of naphthaleneacetic acid (NAA).

Aspergillus niger appears to metabolize NAA to 5-hydroxy NAA. Other possible products are the 4- and 6-hydroxy NAA isomers, as well as other phenolic or naphtholic compounds (Clifford & Woodcock, MRID 005011538). Because the metabolites identified in these studies are structurally related, hydroxylation thus appears to be a major route of degradation of NAA.

A coliform bacterium and two animal pathogens (Staphylococcus aureus and human type tubercle bacilli) are inhibited by NAA at 50 to 300 ppm, where as avian type tubercle bacilli are not inhibited by NAA at 50 ppm (Loveless et al., MRID 005005277) (Ukita et al., MRID 005010797). A yeast, Saccharomyces cerevisiae, is inhibited 13 to 58 percent by NAA at 100 to 500 ppm. In addition, large-cell mutants result from the induction of polyploidy (Doi et al., MRID 005008826). Two mutants of Neurospora crassa are inhibited 12 to 68 percent by NAA at 10 to 50 ppm, but a wild type control strain was not studied (Klein, MRID 005010966). An algae, Chlorella pyrenoidosa, is inhibited 40 to 80 percent by NAA at 46 to 372 ppm (Gramlich & Frans, MRID 005009027).

Thus, a wide range of microorganisms are inhibited by NAA at 10 to 500 ppm which are concentrations far in excess of the highest expected level in the soil (0.08 ppm). Most studies dealt with mutants, animal pathogens, or soil microorganisms and therefore are of questionable importance. While none of the studies reported the source and purity of the NAA used, these studies are sufficient to provide an indication that high concentrations of NAA will inhibit microorganisms.

In summary, although very little data are available to form a profile of the environmental fate of NAA, 5-hydroxy NAA is a suspected fungal metabolite of NAA. At very high concentrations, NAA is capable of inhibiting bacteria, fungi, and algae and also of inducing polyploid mutants. The available data suggest that currently approved NAA application rates will not have an effect on soil microorganisms.

Based on the minor use status of these chemicals and because the Agency would not normally require the above data on microorganisms, the above studies are for information only and need not be cited or submitted by applicants.

No other data exist on the environmental fate of these chemicals. Because these minor use chemicals, are applied at very low application rates (25 to 35 grams per acre), and are applied only once or twice per year, the Agency has determined that exposure to humans and wildlife is likely to be minimal. Accordingly, further environmental fate data requirements have been waived.

## C. Exposure Profile

### 1. Introduction

1-Naphthaleneacetic acid (NAA) is registered for use on orchard crops and ornamentals as a growth regulator. Its total annual use is between 7,000 to 15,000 pounds. Thirty to fifty percent of this production is used primarily on apples and 20 to 30 percent of this production is used on pears. Ten to thirtypercent of the yearly production account for ornamental uses, with use on olive and pineapple crops each accounting for less than 10 percent of the pounds of this production. On apples and pears, NAA is applied to chemically thin the fruit or to prevent preharvest drop. Ornamental uses are mainly for root growth stimulation and for delaying leaf drop. The present formulations of these chemicals are listed in table 2.

TABLE 2

REGISTERED FORMULATIONS OF NAA, ITS SALTS, ESTER & ACETAMIDE

| CHEMICAL | FORMULATION TYPE | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | D (%ai) | EC (lb/gal ai) | SC/L (lb/gal ai) | SC/S (%ai) | WP (%ai) | RTU (%ai) | CR (%ai) | PrL (%ai) |
| NAA | 0.2 | 0.016 | 0.04-0.28 | | 3.5 | | | |
| Sodium Salt | | | | 3.5-98 | 2.0 & 7.11 | | 98 | |
| Potassium Salt | | | | | | | | |
| Ammonium Salt | | | 0.44 & 1.76 | | | | | |
| Ethyl Ester | | | | | | 1.0 | | 1.0 |
| Acetamide | 0.4 | | 0.176 | | 8.4 | | | |

D=dust; EC= emulsifiable concentrate; SC/L= soluble concentrate/liquid; SC/S= soluble concentrate/solid; WP= wettable powder; RTU= ready-to-use; CR= crystalline; PrL= pressurized liquid; IM= impregnated material

NAA formulations (D, WP, EC, SC/L, SC/S, and Cr) are applied as foliar sprays to fruit crops, either aerially or using ground equipment that directs the spray up into the trees. Applications for ornamental uses include soil drench (SC/L), manual spraying (WP and SC/L), and dipping plant cuttings (D and SC/L).

## 2. Foliar Applications

No data are available to assess the environmental fate of NAA and subsequent potential for exposure to humans and wildlife. Similarly, no data are available to quantify the exposure that applicators and their helpers may experience in the handling and application of NAA.

All formulations, except the RTU and PrL formulations, are registered for use as foliar sprays. While spray drift from high-pressure spray equipment and aerial applications may expose humans, livestock, and wildlife outside of the application site, the major exposure will be to workers mixing, loading, and applying NAA. Respiratory and dermal exposure may result from "puff back" of the dry formulations during mixing; ocular exposure could occur during mixing of the liquid formulation. The use of protective clothing should eliminate any hazard associated with this route of exposure.

These chemicals are usually applied by a single person using air blast equipmentcontrolled from a tractor for 8 to 10 hours per day. Mixing/loading of the chemicals and refueling of the tractor occurs approximately 12 to 15 times per day, averaging 10 minutes per stop. A second individual, driving a supply truck, may be involved in application. This second individual may be exposed to the spray drift or solution for not more than 5 to 10 minutes for each hour of spraying.

The air blast equipment used to with these chemicals will apply 200 to 300 gallons per acre, with spray particles reaching a height of up to 25 feet, depending on the orientation of the upper bank of nozzles, air direction vanes on the top of the sprayer, wind conditions, etc.

Regular work clothes are usually worn by the tractor driver and the refilling helper. Coveralls may be worn by some workers and rubber gloves may be worn by individuals handling the concentrated product. Approximately 25% of the tractor operators work in enclosed cabs.

### 3. Soil Drench and Dip Applications

Ornamental uses of NAA include a soil drench to stimulate rooting and a dip for plant cuttings. Dermal exposure would result to workers during these procedures. However, such exposure will be extremely small considering the small amount of active ingredient found in use dilutions of these chemicals. The half-life of NAA in potting soil and on cut plant surfaces is not known.

## D. Summary of Data Gaps

Because of the low application rate and the minor use status of these chemicals the Agency has determined that further environmental fate testing is not required.

# CHAPTER VI: TOXICOLOGY

A. Toxicology Profile
B. Human and Domestic Animal Hazard Assessment
C. Summary of Data Gaps

## A. Toxicology Profile

### 1. TECHNICAL CHEMICALS

### a. Napthaleneacetic Acid (NAA)

### 1) Acute Effects

No data were available to assess the acute oral, acute dermal and acute inhalation toxicities of technical NAA, nor are data available to assess the primary eye irritation, primary dermal irritation, and dermal sensitization potential of technical NAA. The above acute toxicity tests must be performed on technical NAA and are so identified in Chapter III of this Standard.

### 2) Subchronic Effects

In a range-finding study (Huntingdon Research Center, MRID GS-0023-001) male and female Sprague-Dawley rats were given 250, 1000 or 4000 mg/kg/day technical NAA by gavage for 10 consecutive days. All the animals at the highest dose and one female in the 1000 mg/kg/day dose group died after two to three days. Clinical signs of toxicity which preceded death, included dyspnea, ataxia, lethargy and prostration. Dose related depressions in body weight gain and food consumption were observed. The incidence of gross pathological alterations, which included discolored lungs, liver or kidneys, distended bladder and G.I. tract, was greater in the treated groups. From the doses tested, 250 mg/kg/day appeared to be the maximum tolerated dose.

In another range finding study (Verschuuren et al., MRID 005008106) male and female Wistar rats were fed diets containing 0, 50, 250, 1,250 or 7,500 ppm technical 1-NAA for two weeks. Evidence of toxicity included liver glycogen depletion at the two highest doses, accompanied by a slight increase in relative liver weight at 7500 ppm and a nonsignificant increase in serum SGPT activity at this dose. In addition, an increase in the relative kidney weight at 1250 and 7500 ppm was significant in males. Histological examination demonstrated some changes in the tubular epithelial cells of the kidneys in rats at the 2 highest doses. These changes in the renal tubules were indicative of proteinosis which is caused by the leakage of proteins from the glomeruli and subsequent resorption in the proximal tubes.

Verschuuren et al. (MRID 005008106) also investigated the effect of feeding technical 1-NAA (% A.I. unspecified) in the diet at 0, 200, 1000 or 5000 ppm to male and female rats for 90 days. This study provided supplemental information about the subchronic toxicity of 1-NAA in rats. A reduction in growth and food consumption was observed in males at the highest dose and was accompanied by an increase in the relative liver weight and an induction of liver microsomal enzymes in these same animals. These results demonstrated a dose related reduction in liver glycogen depletion (which was more severe in females) and a centrolobular decrease in liver glucose-6-phosphatase at all levels. Because of these findings, a NOEL could not be determined from this study. The authors indicated that the renal tubular changes observed in the two week range finding study were not observed at 200, 1000 or 5000 ppm in the 90 day study.

The subchronic oral toxicity of technical NAA in rats could be adequately assessed in a 90-day feeding study (CDC RESEARCH, MRID GS-0023-002) in which male and female Sprague-Dawley rats were given 0, 50, 150 or 500 mg/kg/day of technical NAA in the diet. In this study, body weight gain depression (approximately 12 to 13%) was observed in males and females at 500 mg/kg/day. In addition, a significant increase in both relative and absolute liver weight was observed in females at the highest dose. The data indicated a NOEL of 150 mg/kg/day. The authors reported that there was no evidence microscopically of hepatic centrolobular glycogen depletion as reported previously (Veschuuren et al., MRID 005008106). This study fulfills the subchronic oral toxicity data requirement in rats.

In a six-month subchronic oral toxicity study (Elars Bioresearch Laboratories, MRID GS-0023-031) technical NAA (in gelatin capsules) was given to male and female beagle dogs at doses of 0, 50, 150 and 300 mg/kg/day. Glycogen depletion and degenerative changes in the liver were observed at 150 and 300 mg/kg/day. Also, two of eight dogs at 50 mg/kg/day showed slight evidence of pericholangitis that was similar in nature to lesions in the livers of dogs given 150 and 300 mg/kg/day. This study indicates that the dog is more sensitive to the toxic effects of NAA than the rat. A NOEL of 50 mg/kg/day is established from this study based on the following considerations:

- pericholangitis at the lowest dose level was slight and reflects a very low to no effect on liver function,

- the lesion is reversible and reflects a slight inflamation process resticted to the portal areas of the liver

- while dose related, the lesion is considered to be mild.

No further subchronic oral testing in the dog is required.

An adequate study was available to assess the teratogenic potential of technical NAA in rats. (Huntington Research Center, MRID GS-0023-044). In this study technical NAA at concentrations of 0, 10, 50 or 250 mg/kg (in supension with 0.05% sodium carboxymethylcellulose) was given (by gavage) to pregnant CD rats on gestation days 6 through 15. No teratological effects were observed. A decrease in maternal body weight was observed at 250 mg/kg, however this was not accompanied by fetotoxicity. The data indicated that the NOEL for teratology for NAA technical in rats is greater than 250 mg/kg. The NOEL for maternal toxicity was 50 mg/kg. This study fulfills the teratology data requirement for NAA in one mammalian species. Testing in a second species is required.

### 3) Chronic Effects

In a 19 month oncogenicity study (Bionetics Research Labs, MRID 005010016) NAA, at 100 mg/kg by a single subcutaneous injection (in DMSO) or at 215 mg/kg by oral intubation (in 0.5% gelatin) for 21 days and in the diet at 517 ppm for the remainder of 18 months, was evaluated for carcinogenicity in two hybrid strains of mice, B6C3F1 and B6AKF1. No significant difference was observed between the tumor incidence of mice treated with NAA and mice in the negative control groups. However, the number of animals tested in each group was too small to adequately evaluate the carcinogenic potential of NAA in mice. In addition, the sensitivity of this assay is diminished since, one of the chemicals used as a positive control, isosafrole, gave equivocal evidence of oncogenicity. While this study does not meet the Agency's current requirements for oncogenicity testing, it does provide an initial screen of the oncogenic potential of NAA. Since positive results were not demonstrated and since these chemicals are minor use chemicals, the Agency has determined that further oncogenicity testing will not be required at this time.

### 4) Mutagenic Effects

Adequate data were available to assess the mutagenic potential of technical 1-NAA in bacterial assays. In a study, (Pharmakon Laboratories, MRID GS-0023-041) 1-NAA at concentrations of 0.5, 2, 8, 40, 200, 1000 or 5000 ug/plate was non-mutagenic in Salmonella typhimurium strains TA 1535, TA 1537, TA 1538, TA 98 and TA 100 when tested with and without metabolic activation. This assay detects reverse mutations resulting from base pair substitution or frameshift events. The data can be considered sufficient to fulfill the mutagenicity data requirement for microbial point mutation testing.

In another study, (Pharmakon Labortories, MRID GS-0023-040) technical 1-NAA (in water or 10% DMSO) at concentrations of 10, 20 and 40 ug/plate did not produce a zone of inhibition when added to cultures of Escherichia coli DNA repair deficient strain P 3478 or DNA repair competent strain W3110, with and without metabolic activation. Positive controls, ethylmethanesulfonate and diethylnitrosamine did cause zones of inhibition under similar testing conditions. The lack of a zone of inhibition with 1-NAA in this assay should be interpreted as demonstrating that NAA does not interact with DNA in Escherichia coli.

Studies were available to assess the effects of technical 1-NAA in yeast. (Pharmacon Laboratories, MRID GS-0023-037; Pharmacon Laboratories, MRID GS-0023-038; Pharmacon Laboratories, MRID GS-0023-039). In these assays, technical 1-NAA was evaluated for its effects on mitotic crossing over, reverse mutation and gene conversion in Saccharomyces cerevisiae strain D-7.

In the mitotic crossover assay, 1-NAA at concentrations of $10^{-6}$ to $10^{-2}$ M did not have mutagenic activity in heteroallelic ade 2-40/ade 2-119 diploid strain D-7 Saccharomyces cervisiae, when tested without metabolic activation.

In a reverse mutation assay, 1-NAA at concentrations of $10^{-6}$ to $10^{-2}$M did not have mutagenic activity in homoallelic ilv - I - 92/ilv - I- 92 diploid strain D-7 Saccharomyces cervisiae, when tested without metabolic activation.

In the mitotic gene conversion assay 1-NAA at concentrations of $10^{-6}$ to 2.1 $x10^{-2}$M did not have mutagenic activity in heterallelic diploid trp 5-12/trp 5-27 strain D-7 *Saccharomyces cervisiae*, when tested without metabolic activation.

The above assays indicated that 1-NAA was nontoxic to the yeast at concentrations as high as $10^{-2}$M. This finding and the lack of genetic activity in all three assays indicate that 1-NAA is inactive in *Saccharomyces cervisiae* strain D-7 yeast.

In another study (Doi et al., MRID 005008826), NAA was evaluated for its ability to induce large cell mutants in *Saccharomyces cerevisiae* haploid strain H 40. This study suggests that NAA, at 500 ug, induced changes in the ploidy of these cells. These data cannot be interpreted as indicating that NAA has genetic activity in this strain of yeast because a change in ploidy does not necessarily reflect an effect on DNA.

Supplementary data were available to evaluate the *in vivo* cytogenetic effects of technical 1-NAA (Pharmakon Laboratories, MRID GS-0023-042). In a study, male and female mice were pretreated for two days with 60 or 125 mg/kg of NAA (in water) by intraperitoneal injection. Six hours after the second dose the animals were killed, their femurs were removed and the bone marrow aspirated. Polychromatic erythrocytes were counted for the presence of micronuclei (an indication of chromosomal breaking effects of the chemical). The results for NAA were negative while TEM (triethylenemelamine), the positive control, gave a statistically significant increase (over vehicle control) in the number of micronuclei per 1000 polychromatic erythrocytes. Since no cell counts were made, the sensitivity of this assay is diminished. It is possible that NAA was toxic to the cells; in this event, an increased number of micronuclei may not have been detected.

A dominant lethal study with technical 1-NAA is available (Pharmakon Laboratories, MRID GS-0023-043). In this study male rats were given 1-NAA in 0.25% methylcellulose by oral intubation at concentrations of 125, 250 or 500 mg/kg for five consecutive days. Subsequently the males were mated with virgin females. Matings were repeated for a total of eight weeks. Vehicle and positive control (triethylenemelamine (TEM) groups were run under similar testing conditions. The results indicated that NAA did not produce dominant lethal effects in male rats as measured by preimplantation and post-implantation losses. Post-implantation fetal deaths were significantly increased after the first four matings in dams mated to males given TEM, the positive control. This study is adequate to assess the dominant lethal effect of NAA. It can be concluded that NAA, at concentrations as high as 500 mg/kg, does not produce dominant lethal effects in rats.

The above identified studies are adequate to evaluate NAA for its mutagenic potential. Although some of the studies, by themselves, were insufficient to assess the mutagenic potential of NAA, as a whole the data indicate that NAA has a low potential for inducing genetic effects. Further mutagencity testing with NAA, its salts, ester and acetamide is not required.

### 5) Metabolic Effects

An adequate metabolism study is available with carboxyl-labeled naphthaleneacetic acid $C^{14}$(1-NAA-$C^{14}$) in rats. (Letcho and Brouwer, MRID 000004942). In this study, male rats were given single oral doses of 0.1, 1.0, 100 or 250 mg of 1-NAA-$C^{14}$ (in sodium hydroxide). Radioactivity in the urine and feces was monitored daily for three days. The results indicated that 71 to 90% of the radiolabel was excreted in the urine and 3 to 21% was excreted in the feces within three days. The two major urinary metabolites (70 to 93%) were naphthaceturic and naphthacetyglucosiduronic acids. It was observed that at the lower doses, approximately 90% of the radioactivity was excreted in the urine in the first 24 hours.

In this study, rats with cannulated bile ducts were given single oral doses of 0.1 or 100 mg of 1-NAA-$C^{14}$. The radioactivity of the urine and bile was monitored every two hours (up to six hours). The results showed that 4 to 21% of the radiolabel collected during this time was biliary, while 1 to 53% of it was urinary. At the high dose, the major metabolite was the glucuronic acid conjugate (i.e. naphthylglucosiduronic acid) while at the low dose the major metabolite was the glycine conjugate (i.e. napthylaceturic acid). In summary, this study indicated that 1-NAA and its metabolites are rapidly excreted in the urine and feces of rats. In addition, it was shown that rats have a greater capacity for glucuronic acid conjugation.

Additional information concerning the metabolism of 1 NAA-$C^{14}$ in man, primates, rodents, cat and bat was available (Dixon et al., MRID 005008052). In this study 100 mg/kg of 1-NAA-$C^{14}$ (in sodium hydroxide) was given intramuscularly to 6 primate species, intraperitoneally to the cat, rat and bat, and orally to the rabbit. In addition, 5 mg of 1-NAA-$C^{14}$ (orally) was given to a man. In most species tested 60 to 100% of the radioactivity was excreted in the urine by 48 hours. The glucuronic acid conjugate was the major urinary metabolite in man, rhesus monkey, marmoset, rabbit, rat and fruit bat. In the cat, no glucuronic acid conjugate was excreted; taurine and glycine conjugates were the major excretion products.

Also, in this study female rats with cannulated bile ducts were given 5 to 500 mg/kg 1-NAA-$C^{14}$ intraperitoneally. After three hours, 10 to 44% of the radioactivity was present in the bile and 0.6 to 32% was present in the urine. At the highest doses, glucuronic acid conjugation predominated whereas at the lower doses there appeared to be a similar amount of glycine and glucuronic acid conjugation.

The above data are adequate to characterize the metabolism of 1-NAA. It is expected that the ethylester of 1-NAA and naphthaleneacetamide will be metabolized similarly once they are degraded to their respective alcohol and salt, and NAA by gastro-intestinal esterases and amidases. No additional metabolism studies are required with these chemicals.

### b. Salts

#### 1) Acute Effects

No data were available to assess the acute oral, acute dermal and acute inhalation toxicities of the technical sodium, potassium or ammonium salts of NAA. Since it is expected that the acute toxicities of the sodium and potassium salts of NAA will be comparable to those of the acid, testing with these chemicals is not required. The acute toxicity of the ammonium salt will be assessed once the data are available for the acid.

No data were available to assess the primary eye irritation, primary dermal irritation and dermal sensitization potentials of the technical sodium, potassium or ammonium salts. It is expected that sodium and potassium salts of NAA will have similar eye and dermal irritation potentials and dermal sensitization potentials as the acid; therefore, testing of these chemicals is not required.

The ammonium salt is not expected to cause dermal irritation or dermal sensitization greater than that resulting from exposure to the acid; therefore, these tests are not required. However, the ammonium salt may have eye irritant properties that are greater than those caused by exposure to the acid; therefore, an eye irritation study with this salt is required.

#### 2) Subchronic/Chronic/Mutgenicity Effects

Subchronic, chronic and mutagenicity toxicity testing with the technical sodium, potassium or ammonium salts is not required, since the subchronic, chronic and mutagenic toxicity of these chemicals is expected to result from exposure to the acid.

### c. Ester

#### 1) Acute Effects

An adequate acute oral toxicity study in rats (Affiliated Medical Research, MRID GS-0023-048) was available with technical NAA- ethyl ester. In this study, NAA-ethyl ester in water, was given to three groups of male rats by oral intubation. The $LD_{50}$ was determined to be 3580 $\pm$ 333.3 mg/kg. Gross autopsy findings from the animals that died during the study included hemorrhagic stomach, intestines and lungs, fluid and gas filled intestines and stomach, discolored spleen and kidneys, mottled liver, dialated mesenteric blood vessels, wet genital area and bloody nose. These data are sufficient to fulfill the acute oral toxicity data requirement for the technical ethyl ester of NAA and place this product in Toxicity Category III.

An adequate acute dermal toxicity study in rabbits with technical NAA ethyl ester was available. (Affiliated Medical Research, MRID GS-0023-047). In this study the acute dermal $LD_{50}$ in male albino rabbits was determined to be greater than 5 g/kg. No mortality was observed when four male albino rabbits were given 24 hour dermal exposure to 5 g/kg of technical NAA-ethyl ester. The test material was applied to the shaved, unabraded skin under an occlusive rubber wrap. No signs of toxicity or gross pathological alterations were observed. These data are sufficient to fulfill the acute dermal toxicity data requirement for the technical ethyl ester of NAA and place this product in Toxicity Category III.

Sufficient data were available to assess the acute inhalation toxicity of technical NAA ethyl ester in rats. (Affiliated Medical Research, MRID GS-0023-046). In this test, the $LC_{50}$ was determined to be greater than 206.5 mg/L. No mortalities were observed when six male albino rats were given one hour inhalation exposure to a nominal concentration of 206.5 mg/L of aerosol technical ethyl ester of NAA in a 50% suspension with water. Following exposure, signs of toxicity were irritation and lethargy. The animals appeared normal by the second day. No gross pathological alterations were observed. These data are adequate to fulfill the acute inhalation toxicity data requirement and place technical ethyl ester of NAA in toxicity category IV.

The above data indicate a low acute toxicity potential for the ethyl ester in humans.

Adequate data were available to evaluate the primary eye irritation potential of technical NAA-ethyl ester. (Affiliated Medical Research, MRID GS-0023-045). In this study, 0.1 ml of the test chemical was instilled into the left conjunctival sac of the eyes of nine male albino rabbits. Six eyes were washed two or four seconds after instillation. No irritation was observed to the cornea, iris or conjunctiva in washed and unwashed eyes. The primary eye irritation score was 0 (out of a possible 110). These data are sufficient to fulfill the primary eye irritation data requirement for the technical ethyl ester of NAA. The chemical should not be considered a primary eye irritant and it should be placed in Toxicity Category IV.

Since the ethyl ester did not produce eye irritation in rabbits and since no gross pathological skin alterations were observed in rabbits in an acute dermal toxicity study with this chemical, it is expected that the ethyl ester will have a low potential for dermal irritation in humans. No further dermal irritation testing is required.

No data were available to assess the dermal sensitization potential of the ester. It is expected that the dermal sensitization potential of this ester will be similar to that of the acid; therefore, additional testing is not required.

### 2) Subchronic/Chronic/Mutagenic Effects

In an inadequate study by Finch and Hartzell (MRID 005022160), female mice were fed diets containing 0, 0.95, 9.5, 29 or 86 ppm of alpha naphthalene acetic acid methyl ester for 1-1/2 to 2 years. No significant differences in body weight gain or survival and no pathological alterations attributed to the test material were reported. The study was insufficient to assess the chronic toxicity of NAA; the number of animals treated at each dose level was low (20 mice/dose) and only females were tested. Animals were housed in group cages and weighed by group; individual body weights were not determined. There was no food consumption data, clinical testing was not performed, and histopathological examinations were not made.

Finch and Hartzell (MRID 005022160) also investigated the reproductive effects of alpha naphthalene acetic acid methyl ester in the diet at concentrations of 0, 0.95, 9.5 29 or 86 ppm in mice. No reproductive toxicity, through the third generation was observed however, the study is insufficient to evaluate the reproductive toxicity of NAA. The number of animals bred was low and females were bred to yield only one litter. Inadequate information was available for fertility, lactation and viability. No body weight data were available for the pregnant dams, and no data were available for gestation. There were no observation data for the pups; there were no data to indicate the number of pups found dead at birth. The data for pup body weight was inadequate and there were no pathology data for the pups. In addition, the authors indicated that no toxicity was observed even at the highest doses.

While the above studies were performed with the methyl ester and do not meet with current scientific standards, the Agency has determined that additional reproductive and chronic feeding testing with technical NAA will not be required at this time, since these chamicals are minor use chemicals and available data do not indicate major concerns in these areas.

Subchronic, chronic and mutagenicity toxicity testing with the technical ethyl ester of NAA is not required, since the subchronic, chronic and mutagenic toxicity of this chemical is expected to result from exposure to the acid, through in vivo metabolism.

d. Acetamide

1) Acute Effects

Because these are minor use chemicals no acute testing with technical naphthaleneacetamide is required at this time.

2) Subchronic/Chronic/Mutagenic Effects

Subchronic, chronic and mutagenicity toxicity testing with the technical naphthaleneacetamide is not required, since the subchronic, chronic and mutagenic toxicity of this chemical is expected to result from exposure to the acid, through in vivo metabolism.

2. FORMULATED PRODUCTS

a. Soluble Concentrates

1) NAA

Because these are minor use chemicals, except for the primary eye irritation study mentioned below, no acute toxicity testing will be required at this time.

Primary eye irritation testing with soluble concentrates containing greater than 50% petrolium oil or diacetone is required.

2) Salts

Sodium Salt

Because these are minor use chemicals, no acute toxicity testing will be required at this time.

Potassium Salt

Because these are minor use chemicals, except for the primary eye irritation study mentioned below, no acute toxicity testing will be required at this time.

Primary eye irritation testing with soluble concentrates containing the greater than 25% isopropanol is required.

Ammonium Salt

Because these are minor use chemicals no acute toxicity testing will be required at this time.

3) Ester

An adequate acute oral toxicity study in rats with a soluble concentrate containing 15.1% NAA-ethyl ester was available. (Affiliated Medical Research, MRID GS-0023-035). In this study, the test material (in water) was given to three groups of male rats by oral intubation. The $LD_{50}$ was determined to be 5585 ± 760 mg/kg. Signs of toxicity included hypoactivity in one rat at the highest dose (10g/kg), from one hour after dosing until death. Gross autopsy findings from the animals that died during the study included hemorrhagic stomach, intestines and lungs, fluid and gas filled intestines and stomach, blanched and slightly pitted kidneys, mottled spleen, bloody nose and stained genital area. These data are sufficient to fulfill the acute oral toxicity data requirement for the 15.1% soluble concentrate of NAA-ethyl ester and place the product in Toxicity Category IV.

An adequate acute dermal toxicity study in rabbits was available with a soluble concentrate containing 15.1% NAA-ethyl ester (Affiliated Medical Research, MRID GS-0023-032). In this study, the $LD_{50}$ was determined to be greater than 5 g/kg. No mortality was observed when four male albino rabbits were given 24 hour dermal exposure to 5 g/kg of the product. The test material was applied to the shaved, unabraded skin of the rabbits under an occlusive rubber wrap. No signs of toxicity were observed. Gross pathological examination indicated eschar formation at the site of application. These data are sufficient to fulfill the acute dermal toxicity data requirement for the 15.1% soluble concentrate of NAA-ethyl ester and place this product in toxicity Category III.

Adequate data were available to assess the acute inhalation toxicity of a soluble concentrate containing 15.1% NAA ethyl ester in rats. (Affiliated Medical Research, MRID GS-0023-034). In this study, the $LC_{50}$ was determined to be greater than 217.1 mg/L. No mortalities were observed when 6 male albino rats were given one hour inhalation exposure to a nominal concentration of 217.1 mg/L of the soluble concentrate in a 50% w/v emulsion with water. Following exposure, signs of toxicity were irritation and lethargy. The animals appeared normal by 8-24 hours after exposure. No abnormal gross pathological alterations were observed. These data are sufficient to fulfill the acute inhalation toxicity data requirement for the 15.1% soluble concentrate of NAA ethyl ester and place this product in Toxicity Category IV.

The above data indicate a low acute toxicity potential for the 15.1% ethyl ester in humans.

Adequate data were available to evaluate the primary eye irritation potential of a soluble concentrate containing 15.1% of NAA-ethyl ester. (Affiliated Medical Research, MRID GS-0023-033). In this study the test chemical was determined to be a primary eye irritant. When 0.1 ml of the test material was instilled into the left conjunctival sac of the eyes of nine male albino rabbits (with six of the eyes being washed two to four seconds after instillation) corneal opacity that persisted for at least seven days was observed in eight out of nine eyes. In addition, moderate to severe irritation of the conjunctiva and iris persisted for at least seven days in some animals. At 14 days, damage that was described as irreversible by the pathologist was observed. These data are sufficient to evaluate the primary eye irritation potential of the 15.1% soluble concentrate of NAA-ethyl ester and place the product in Toxicity Category I; indicating that the product is corrosive and may cause irreversible eye damage in humans.

No data were available to evaluate the primary dermal irritation or dermal sensitization potential of products containing 15.1% of the ethyl ester. Testing is not required at this time.

4) Acetamide

Because these are minor use chemicals, except for the primary eye irritation study mentioned below, no acute toxicity testing will be required at this time.

Primary eye irritation testing with soluble concentrates containing greater than 50% isopropanol and greater than 50% fertilizer is required.

b. Wettable Powders/Dusts

Because these are minor use chemicals no acute toxicity testing will be required at this time.

c. Pressurized Liquids

Because these are minor use chemicals no acute toxicity testing will be required at this time.

## B. Human and Domestic Animal Hazard Assessment

The present uses of these chemicals indicate that the actual residues on foods would be extremely low. Actual residues and theoretical calculations of residues, presented in the Environmental Fate chapter, confirm that residues will be extremely low.

Despite the fact that the method of application will result in high exposure to the spray, the very low amounts of active ingredient in the spray will result in a low exposure.
Acute exposure of applicators to the concentrated form of these chemicals during mixing/loading constitutes a scenario of concern to the Agency. Data which demonstrate the acute toxicity category associated with the technical chemicals are the Agency's primary concern and these concerns are reflected in the Agency's data requirements.

## C. Summary of Major Toxicology Data Gaps

Many of the studies which have been reviewed meet the Agency's current requirements. Some studies (e.g., oncogenicity, reproduction) are inadequate but do not indicate major concerns in these areas. Because the available data do not indicate major toxicological concerns and because these are minor use chemicals with low dietary and applicator exposure, the Agency has determined that no further testing, except for some acute and irritation studies and a teratogenicity study listed in Chapter III, will be required at this time.

# CHAPTER VII: RESIDUE CHEMISTRY

A. Residue Chemistry Profile
B. Summary of Data Gaps

## A. Residue Chemistry Profile

Naphthaleneacetic acid is marketed in the U.S. as a plant growth regulator to control fruit drop or thinning on apples, pears, quinces, and olives and to control flower induction on pineapples. Tolerances have been established for NAA on apples, pears, and quinces at 1 ppm; on olives at 0.1 ppm; and in or on pineapples at 0.05 ppm (as the sodium salt) (40 CFR 180.155). Tolerances have also been established for the ethyl ester on apples and pears at 1 ppm and 0.1 ppm on olives (40 CFR 180.309). Tolerances have also been established for the acetamide on apples and pears at 0.1 ppm (40 CFR 180.309). No tolerances are pending. No CODEX tolerances exist for these chemicals.

The major residue in olives is NAA, the parent compound. Metabolites in olives are 1-naphthaleneacetylaspartic acid (NAAsp) and B-D-glucose-1-naphthaleneacetate (NAG) (Crosby et al., MRID 000004943). The major residue in apples and pears is B-D-glucose-1-naphthaleneacetate, followed by 1-naphthaleneacetylaspartic acid, and then by NAA (Bukovac et al., MRID 005009196). Although no metabolism data are available on pineapples, data on other fruits indicate that NAG, NAAsp, and NAA would be the residues of concern, although not necessarily in that order. Metabolism data on apples can be applied to quinces since these two fruits are related and quinces are a minor crop use for these chemicals. The metabolism of NAA in plants is adequately defined and no further testing is required. Metabolism data on related compounds (i.e. the salts, ester, and amide of NAA) are not needed if data showing rapid dissociation or hydrolysis to the acid are submitted.

The two major metabolites in rat urine are the conjugates of NAA with glucuronic acid and with glycine (Lethco et al., MRID 000004942; French et al., MRID 005007966; Dixon et al., MRID 005008052; Dixon, MRID 005008057). Metabolites in excrement of the hen are conjugates of NAA with taurine and ornithine (Idle et al., MRID 005008070). The major and minor metabolites in human urine are 1-napthylacetylglucuronide and 1-naphthylacetyltaurine, respectively (Dixon et al., MRID 005008052). No ruminant metabolism study is available. It is concluded that the metabolism of NAA in animals is adequately defined, provided residues do not occur in feed items.

Adequate analytical methods are available for determination of residues and enforcement of tolerances for 1-naphthaleneacetic acid on olives (Crosby et al., MRID 000004943; Zweig et al., MRID 000004916), for the ethyl ester on olives, and for 1-naphthaleneacetamide on apples (Sigrist, MRID 005007967; Cochrane et al., MRID 005020083), pears and olives. Adequate analytical methods are available for the determination of NAA itself on apples (Randall, MRID 005002768; Cochrane et al., MRID 005008121; Bache et al., MRID 005008068), pears, and pineapple (Young et al., MRID 000004946), and for the ethyl ester itself (plus NAA) on pears (Amchem Products, MRID GS-0023-012; Amchem Products, MRID GS-0023-019; Amchem Products, MRID GS-0023-036) and apples. No analytical methods are available for quinces. Available residue data indicate that residues in olives would be less than 0.1 ppm after treatment with Fruit Fix Super Concentration 800. No detectable residues are expected to occur in apples, pears, and olives after treatment with Tre-Hold Sprout Inhibitor A112. Lack of residue data on representativeformulations and uses constitutes a data gap. The limited data which are available indicate that no residues will result in meat, milk, poultry, or eggs from the registered uses. There are no records in EPA or FDA of incidents involving the enforcement of the tolerances.

B. Summary of Data Gaps

1. Dissociation or hydrolysis data on all chemicals.

2. Data indicating whether residues in plants of esters, salts and acetamides of NAA degrade rapidly to NAA.

3. Additional residue data reflecting the registered uses for apples and pears representative of the chemical forms of NAA and registered formulations.

4. Residue data on pineapples and olives are requested which reflect currently registered uses and formulations.

If the data required in 1 and 2 indicate that the various chemical forms of NAA are similar from a residue standpoint, then the additional residue data required in 3 and 4 in this summary can be kept to a minimum with specific study requests.

# CHAPTER VIII: ECOLOGICAL EFFECTS

A. Plant Effects Profile
B. Animal Effects Profile
C. Summary of Data Gaps

## A. Plant Effects Profile

The effects of NAA to nontarget aquatic plants is not known. NAA at 620 ppb caused a 50 percent reduction in root growth of soaked pea roots. There was only a 10 percent reduction in root growth when NAA was applied to the hypocotyl or young stem of peas at 500 ppm. (Elliasson, MRID 005007254) NAA reduces growth in cucumber seedlings with a NOEL of 98 ppb (Hilton & Nomura, MRID 005007255). The germination of lettuce, tomato, sugarbeet or dwarf bean was unaffected in their yields when the seeds were treated with 100,000 ppm NAA applied in talc (Croxall & Ogilvie, MRID 005012526). Concentrations of 0.1 ppm in a seed soak, however, delayed or inhibited germination of cotton. NAA at 100 ppm inhibited germination of cotton for 10-14 days without affecting yields (Coats, MRID 005010399).

The concentration of NAA in the spray solution ranges from 10 to 50 ppm for registered fruit crops and also for decidious trees. The extent of exposure to nontarget terrestrial plants is minimal given the low concentration and, therefore, the hazard is judged to be minimal.

## B. Animal Effects Profile

Naphthalene acetic acid (NAA acid) possesses a very low toxicity to Bobwhite Quail when taken as a single oral dose. The acute oral $LD_{50}$ for Bobwhite Quail is greater than 2510 mg/kg (Truslow Farms, MRID GS-0023-024). The acute oral $LD_{50}$ for Mallard Ducks cannot be determined because the use of immature test animals has compromised the validity of this study (Truslow Farms, MRID GS-0023-023).

Naphthalene acetic acid (NAA acid) possesses a very low toxicity to Bobwhite Quail and Mallard Ducks, when taken ingested along with their regular diet. The subacute oral $LC_{50}$ for Bobwhite Quail and Mallard Ducks are both greater than 10,000ppm (Truslow Farms, MRID GS-0023-025; Truslow Farms, MRID GS-0023-026).

While the $LC_{50}$ values for the two freshwater fish and the aquatic invertebrate show that a formulated product, Amchem Tre-Hold Sprout Inhibitor A112, is slightly toxic to aquatic life (Union Carbide Environmental Services, MRID GS-0023-022; Union Carbide Environmental Services, MRID GS-0023-050; Union Carbide Environmental Services, MRID GS-0023-051).

## C. Summary of Major Data Gaps

The Agency cannot presently estimate the hazards to aquatic life posed by the technical chemicals because the proper toxicity tests have not been performed on technical NAA. Before a hazard evaluation can be completed, the Agency must have proper data on the acute toxicity of technical NAA to warmwater and coldwater fish, an aquatic invertebrate, aquatic and terrestrial macrophytes, and algae.

## CASE BIBLIOGRAPHY

### Guide to Use of This Bibliography

1. Content of Bibliography. This bibliography contains citations of all the studies reviewed by EPA in arriving at the positions and conclusions stated elsewhere in this standard. The bibliography is divided into two sections: (1) citations in numerical order that contributed information useful to the review of the chemical and are considered to be part of the data base supporting registrations under the standard, and (2) an alphabetical listing of all documents reviewed by the Agency. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions, and the published technical literature.

2. Units of Entry. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to a published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. Identification of Entries. The entries in this bibliography are sorted by author, date of the document, and title. Each entry bears, to the left of the citation proper, a nine-digit numeric identifier. This number is unique to the citations and should be used at any time specific reference is required. This number is called the "Master Record Identifier" or "MRID". It is not related to the six-digit "Accession Number", which has been used to identify volumes of submitted data; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. This is also to be used whenever a specific reference is needed.

4. Form of the Entry. In addition to the Master Record Identifier (MRID), each entry consists of a bibliographic citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. The bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs. Some explanatory notes of specific elements follow:

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first known submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. This is the third element in the citation. In some cases it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to us in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submissions:

(1) Submission Date. Immediately following the word 'received' appears the date of the earliest known submission, at the time that particular document was processed into the Pesticide Document Management System.

(2) Administrative Number. The next element, immediately following the word 'under', is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission, at the time that particular document was processed into the Pesticide Document Management System.

(3) Submitter. The third element is the submitter, following the phrase 'submitted by'. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification. The final element in the trailing parenthesis identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol 'CDL', standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th,123456-AA.

OFFICE OF PESTICIDE PROGRAMS
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| GS0023046 | Affiliated Medical Research (19??) Acute inhalation of tech ethyl ester of NAA in rats. [Contract# 120-2148-113; Undated] (Amchem Products; CDL:099029, EPA Reg. No. 264- 336; PP# 0F2277) |
| GS0023048 | Affiliated Medical Research (19??) Acute oral LD$_{50}$ in rats (technical chemical). [Contract# 120-2148-113; Undated] (Amchem Products; CDL:099029, EPA Reg. No. 264- 336; PP# 0F2277) |

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GS0023033 Affiliated Medical Research (19??) Primary eye irritation of Amchem 72-A112 emulsifiable concentrate 79068. [Contract# 120-2148-113; Undated] (Amchem Products; CDL:099029, EPA Reg. No. 264-336; PP# 0F2277)

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